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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,214	01/10/2003	Susan M. Logan	11041-1	1851

25277 7590 08/23/2005

NATIONAL RESEARCH COUNCIL OF CANADA
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CANADA

EXAMINER

GEBREYESUS, KAGNEW H

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,214

Applicant(s)

LOGAN ET AL.

Examiner

Kagnew H Gebreyesus

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 18 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 59, 60, 62, 71 and 72 is/are pending in the application.
- 4a) Of the above claim(s) 61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 59 and 60 is/are rejected.
- 7) ☐ Claim(s) 62, 71 and 72 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's reply filed on May, 23, 2005 is acknowledged. Claims 1-58, 61, and 67-70 have been cancelled. Claim 59, 60, 62 have been amended. New claim 72 has been entered. Claims 59, 60, 62-66, 71 and 72 are pending in this application. Claims withdrawn. Claims 63-66 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Claims 59-60, 62, 71 and 72 are now under consideration.

Withdrawn- Claim Rejections - 35 USC § 112

The rejection under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn following applicants amendment.

Withdrawn- Claim Rejections - 35 USC § 112

The rejection regarding claims 59, 60, 62 and 71 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn following applicants amendment.

Withdrawn- Claim Rejections - 35 USC § 112

The rejection with regards to claims 59 and 60 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because these claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and/or use the invention has been withdrawn following the amendment clarifying the scope enabled in the specification.

Withdrawn- Claim Rejections - 35 USC § 102

Claims 59 and 60 are rejected under 35 U.S.C. 102(a) as being anticipated by Appelmelk et al.

This rejection is based upon the public availability of a printed publication Claims 59 and 60 are broadly drawn to a mutant strain of *H. pylori*, said mutant strain having deactivated at least one gene encoding any glycosyltransferase involved in the biosynthesis of an *H. pylori* LPS.

Appelmelk et al. disclose an alpha-3-fucosyltransferase knockout mutant strains of *H. pylori* (which is a glycosyltransferase as broadly interpreted) and confirmed the role of this glycosyltransferase in determining the structure and the mechanism underlying LPS diversity in *H. pylori*. The broad interpretation of claims 59 and 60 encompass, glucosyltransferases, galactosyltransferases, fucosyltransferases, heparosyltransferases etc. Therefore the disclosure by Appelmelk et al. clearly anticipates claims 59 and 60 when given the broadest interpretation of these claims. However the amendments to claim 59 has sufficiently addressed the specific invention claimed by applicants. Likewise Wang et al's disclosure does not anticipate the specific mutant strain of claims 59 and 60 as amended.

Maintained - Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 59, and 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Claims 59 and 60 are rejected because the specification, while being enabling for a mutant strain of *H. pylori* having a mutation in the open reading frame 0826 of *Helicobacter pylori* strain 2665 and strain SS1, which lacks the encoded beta-1, 4-galactosyltransferase activity does not reasonably provide enablement for mutant for any galactosyltransferase enzyme from any strain of *H. pylori*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 59 and 60 are so broad as to encompass any *H. pylori* strain containing mutant galactosyltransferase enzyme encompassing any mutant galactosyltransferase including but not limited to a beta-1, 4-galactosyltransferase encoded by the open reading frame 0826. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the number of galactosyltransferases and diverse strains of *H. pylori* broadly encompassed by the claims. Since glycosyltransferases and numerous galactosyltransferases involved in LPS biosynthesis determine LPS structural and functional properties, predictability of a *H. pylori* strain derived from mutations on any one of these galactosyltransferases singularly or in combination can result in obtaining the desired LPS structure requires a knowledge of and guidance with regard to the type(s) of galactosyltransferase(s), if any, are tolerant of modification and which are conserved

(i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the galactosyltransferases mutation relates to the LPS structure. However, in this case the disclosure is limited to an *H. pylori* (HP0826) beta-1, 4-galactosyltransferase mutant strains derived from wild type strain 2665 and strain SS1 in which the 0826 gene is mutated by allelic exchange.

While recombinant and mutagenesis techniques of single genes are known for making a specific bacterial strain, it is not routine in the art to perform multiple types of enzyme modifications, as encompassed by the instant claims (any galactosyltransferase), with a reasonable expectation of success in obtaining a specific LPS structure and the result of such modifications are unpredictable. In addition, one skilled in the art would expect modification of specific galactosyltransferases alone or in combination would result in LPS structures with corresponding epitopes.

The specification does not support the broad scope of the claims which encompass all mutant strains resulting from deactivation of any galactosyltransferase alone or in combination because the specification does not establish: (A) the specific galactosyltransferase that results in a mutant *H. pylori* strain; (B) the result of deactivating any galactosyltransferase; (C) a rational and predictable scheme for modifying any galactosyltransferase gene with an expectation of obtaining the specific claimed mutant *H. pylori* strains enabled by the specification; and (D) the specification provides insufficient guidance as to which of the galactosyltransferases is likely to be successful in obtaining the specific mutant strain(s) of *H. pylori*.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any mutant *H. pylori* strain comprising any number of mutant

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galactosyltransferase(s) alone or in combination. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired mutant *H. pylori* is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

3. Claim 62, 71 and 72 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion:


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagnaw H Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5: 30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Achutamurthy ponnathapura can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kagnew Gebreyesus PhD.


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